COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 22-V-2007
C(2007)2261

NOT FOR PUBLICATION

COMMISSION DECISION

of 22-V-2007

concerning the implementation of conditions or restrictions set out in Article 127a of Directive 2001/83/EC of the European Parliament and of the Council concerning the marketing authorisation for "Thelin - Sitaxentan sodium", a medicinal product for human use, granted by Decision C(2006)3721

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 9(4)(c) thereof,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Articles 33, 34 and 127 (a) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 February 2007,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Thelin - Sitaxentan sodium", which is entered in the Community Register of Medicinal Products under number(s) EU/1/06/353/001-005 and the placing on the market of which was authorised by Decision C(2006)3721 of 10 August 2006, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1)
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1.

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to authorise the amendment of the marketing authorisation. To this effect, Commission Decision C(2007)2262 of 22-V-2007 amending, for the purposes of its extension, the marketing authorisation to the medicinal product "Thelin - Sitaxentan sodium" is simultaneously being addressed to Encysive (UK) Limited.

(3) The marketing authorisation is subject to conditions or restrictions with regard to the safe and effective use of the medicinal product. It is appropriate that implementation of these conditions is ensured by the Member States.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The Member States shall ensure implementation of the conditions or restrictions with regard to the safe and effective use of the medicinal product set out in the Annex.

Article 2

Decision C(2006)3722 is amended as follows:

The Annex is replaced by the text set out in the Annex to this Decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 22-V-2007

For the Commission
Heinz ZOUREK
Director-General

[4] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).